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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,639	10/08/2003	Qinwei Shi	12927-7 LAB	6090

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EXAMINER	
YU, MELANIE J	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/681,639	SHI, QINWEI	
	Examiner	Art Unit	
	MELANIE YU	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *3,4,8,9,14-19,22,23 and 27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-7,10-13,20,21,24-26 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 October 2008 has been entered.

2. Applicant's legible copy of claims filed 7 January 2009 have been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500).

Kang et al. teach a device comprising one or more dry porous membranes, wherein the membranes provide a membrane channel through which the liquid sample can flow by capillary action while reactions take place to determine at least one component in the sample (col. 4, lines 47-38; col. 4, lines 50-65); wherein the platform is formed with sample application means, holds the membrane in place and forms a flow channel upstream of the membrane, the formed channel being in communication with the membrane to permit the liquid to flow in a continuous pathway from the sample application means to the distal end of the membrane (col. 4, lines 50-54). Kang et al. fail to teach the platform formed by face to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in at least one of the hydrophilic surfaces.

Catt et al. teach a test strip (204, Fig. 2) mounted in a plastic platform that has a top and bottom layer (top layer, 200, bottom layer, 201, Fig. 2; col. 23, lines 25-44) to enclose and position a membrane so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact to enclose the membrane in place and including an indent in the bottom surface of the top layer to form a channel to hold the membrane (Fig. 2; col. 23, lines 25-44), in order to provide a good moisture conducive junction between porous membranes. Catt et al. fail to specifically teach the plastic platform being hydrophilic.

Yu teaches a channel that is hydrophilic wherein a hydrophilic matrix may be placed inside the channel (one or more of the embodiments would include a hydrophilic channel wherein a hydrophilic matrix is within the channel, col. 11, lines 32-56), in order to provide sample flow through the channel.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al., a platform having a top and bottom layer that are placed in face to face contact to hold the membrane in place with an indent in the bottom surface of the top layer to form a channel as taught by Catt et al., in order to provide a test strip casing that is inexpensive to produce and easy to assemble. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al., the plastic platform surfaces forming the channel being hydrophilic as taught by Yu, in order to provide an accurate, precise and efficient test strip wherein sample is moved quickly through a channel.

With respect to claims 5, 10 and 24, Kang et al. teach a window in the top of the device for observing the results of a reaction which takes place in the membrane (col. 4, lines 50-56) and Catt et al. teach a window in the top layer of the device (col. 23, lines 34-39).

Regarding claims 11 and 25, Kang et al. teach that a plurality of reagents may be present for detecting one or more analyte (col. 5, lines 1-11).

With respect to claim 20, Kang et al. teach the device containing an upstream detection membrane and a downstream capture membrane (filter elements and wicking

membrane, col. 4, lines 20-38; col. 3, lines 50-61), wherein the detection membrane constructed to filter unwanted components from the sample and containing a mobile labeled detection region which will react with the component to form a reaction product which moves downstream in the detection membrane (although Kang does not specifically teach removing red blood cells, the filter is capable of removing red blood cells if the cells are the unwanted components, col. 3, lines 24-42); a capture membrane downstream of the detection membrane and containing a fixed, immobile capture reagent which will react with and concentrate the reaction product at a capture line (col. 3, lines 50-60), the downstream end of the detection membrane slightly overlapping the upstream end of the capture membrane (col. 5, lines 45-53); the membranes being enclosed in a platform (described above in the explanation of obviousness over Kang et al. in view of Catt et al. further in view of Yu) wherein the sample flows in a continuous path from the application means through the detection membrane to the distal end of the capture membrane (col. 4, lines 50-65).

Regarding claim 33, Kang et al. teach the detection membrane being a glass fiber membrane (col. 6, lines 32-35) and the capture membrane being a nitrocellulose membrane (wicking membrane, col. 6, lines 38-42).

With respect to claim 34, Kang et al. teach the membranes covered with a transparent cover layer (col. 7, lines 23-25).

Regarding claim 35, Catt et al. teach the porous material sandwiched between two transparent layers of polyester film (col. 25, line 63-col. 26, line 5).

2. Claims 1, 2, 5-7, 10, 11, 20, 21, 24, 25, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141).

Kang et al. teach a device comprising one or more dry porous membranes, wherein the membranes provide a membrane channel through which the liquid sample can flow by capillary action while reactions take place to determine at least one component in the sample (col. 4, lines 47-38; col. 4, lines 50-65); wherein the platform is formed with sample application means, holds the membrane in place and forms a flow channel upstream of the membrane, the formed channel being in communication with the membrane to permit the liquid to flow in a continuous pathway from the sample application means to the distal end of the membrane (col. 4, lines 50-54). Kang et al. fail to teach the platform formed by face to face contact of a top and bottom layer having a bottom and top hydrophilic surface, respectively and an indent in at least one of the hydrophilic surfaces.

Catt et al. teach a test strip (204, Fig. 2) mounted in a plastic platform that has a top and bottom layer (top layer, 200, bottom layer, 201, Fig. 2; col. 23, lines 25-44) to enclose and position a membrane so that the bottom surface of the top layer and the top surface of the bottom layer are brought into fixed face to face contact to enclose the membrane in place and including an indent in the bottom surface of the top layer to form a channel to hold the membrane (Fig. 2; col. 23, lines 25-44), in order to provide a good moisture conducive junction between porous membranes.

Segal et al. teach a channel comprising a hydrophilic porous material (col. 13, lines 21-25; col. 12, lines 23-40) wherein the channel is made out of the substrate material which is a non-porous rigid, moisture impermeable material of either polystyrene or glass (col. 9, lines 6-21), in order to provide sample flow through the channel.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al., a platform having a top and bottom layer that are placed in face to face contact to hold the membrane in place with an indent in the bottom surface of the top layer to form a channel as taught by Catt et al., in order to provide a test strip casing that is inexpensive to produce and easy to assemble. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al., the platform surfaces forming the channel being glass, which is a hydrophilic material as taught by Segal et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent substrate material and since the same fluid transport and device structure would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

With respect to claims 5, 10 and 24, Kang et al. teach a window in the top of the device for observing the results of a reaction which takes place in the membrane (col. 4,

lines 50-56) and Catt et al. teach a window in the top layer of the device (col. 23, lines 34-39).

Regarding claims 11 and 25, Kang et al. teach that a plurality of reagents may be present for detecting one or more analyte (col. 5, lines 1-11).

With respect to claim 20, Kang et al. teach the device containing an upstream detection membrane and a downstream capture membrane (filter elements and wicking membrane, col. 4, lines 20-38; col. 3, lines 50-61), wherein the detection membrane constructed to filter unwanted components from the sample and containing a mobile labeled detection region which will react with the component to form a reaction product which moves downstream in the detection membrane (although Kang does not specifically teach removing red blood cells, the filter is capable of removing red blood cells if the cells are the unwanted components, col. 3, lines 24-42); a capture membrane downstream of the detection membrane and containing a fixed, immobile capture reagent which will react with and concentrate the reaction product at a capture line (col. 3, lines 50-60), the downstream end of the detection membrane slightly overlapping the upstream end of the capture membrane (col. 5, lines 45-53); the membranes being enclosed in a platform (described above in the explanation of obviousness over Kang et al. in view of Catt et al. further in view of Segal et al.) wherein the sample flows in a continuous path from the application means through the detection membrane to the distal end of the capture membrane (col. 4, lines 50-65).

Regarding claim 33, Kang et al. teach the detection membrane being a glass fiber membrane (col. 6, lines 32-35) and the capture membrane being a nitrocellulose membrane (wicking membrane, col. 6, lines 38-42).

With respect to claim 34, Kang et al. teach the membranes covered with a transparent cover layer (col. 7, lines 23-25).

Regarding claim 35, Catt et al. teach the porous material sandwiched between two transparent layers of polyester film (col. 25, line 63-col. 26, line 5).

3. Claims 12, 13 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Segal et al. (US 6,300,141), as applied to claims 6 and 20, and Freitag et al. (US 6,214,629).

Kang et al. in view of Catt et al. further in view of Segal et al. teach a device comprising reagents for analyte detection, but fail to teach the analyte being Troponin I.

Freitag et al. teach reagents for the detection of Troponin I in a chromatographic assay (col. 9, line 63-col. 10, line 21), in order to provide detection of cardiac analytes.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Kang et al. in view of Catt et al. further in view of Segal et al., reagents in a porous material for the detection of Troponin I in a blood sample as taught by Freitag et al., in order to provide diagnosis for the cause of chest pain and to determine a cardiac event.

4. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kang et al. (US 5,559,041) in view of Catt et al. (US 6,451,619) further in view of Yu (US 6,723,500), as applied to claims 1, 6 and 20, and Deng (US 6,740,293).

Kang et al. in view of Catt et al. further in view of Yu teach a device comprising a top surface and bottom player in fixed face to face contact to form a flow channel, but fail to teach open areas to inhibit flow into space between the top and bottom layers and protrusions in the top layer that mate with indents in the bottom layer.

Deng teaches a device comprising platform with a top layer (13, Fig. 7) and a bottom layer (12, Fig. 7), wherein the top layer and bottom layer comprise a flow channel having a test strip (col. 6, line 59-col. 7, line 3) wherein the top and bottom layers have open areas, which inhibit flow from the platform flow channel into space between the surfaces of the top and bottom layers (flow is limited to the porous strip, col. 9, lines 19-28; space is between side wall of 12 and test strip 19, which prevents flow between 12 and 13 when they are sealed; openings are created to prevent flow from creeping into handle section, which is between top and bottom layers, col. 7, lines 44-54) and the top surface of the lower layer comprising cylindrical pillars (11a, Fig. 8) that register with cylindrical indents (11b, Fig. 8; col. 6, lines 14-22), in order to provide secure snapping and prevent leaking between the top and bottom layers.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the platform of Kang et al. in view of Catt et al. further in view of Yu, cylindrical pillars that register with indents and open areas that

inhibit flow of the sample between the top and bottom layers as taught by Deng, in order to provide sufficient sealing and prevent leaking outside of the device.

Deng fails to teach the protrusions being rectangular. However, it would have been obvious to one having ordinary skill to provide a different shape to perform the same function of snapping the top and bottom layers together. In re Dailey et al. 149 USPQ 47 (C.C.P.A. 1966).

Response to Arguments

1. Applicant's arguments filed 1 October 2008 and re-filed 7 January 2009 regarding the rejections under 35 USC 103a have been fully considered but they are not persuasive.

2. Regarding the rejections over Kang et al. in view of Catt et al. further in view of Yu, applicant argues that a “channel” is a well-defined structural feature known in the art and based upon the description of the flow channel in figures 1 and 5 of the originally filed disclosure, it would be readily understood by one skilled in the art that the flow channel is empty and does not comprise any membrane. Applicant further argues that the examiner’s comments regarding the exclusion of this subject matter by the claims are not applicable because it is readily evident from the teachings of the description and the figures that it is not possible to have a membrane in the flow channel as the teachings nowhere encompass such an embodiment and the claimed device would not work as described. Applicant’s argument is not persuasive because the claims do not exclude the presence of a membrane from the channel. The claims only require that the liquid sample flows in a continuous pathway from the sample application means to

the distal end of the membrane. The presence of a membrane in the channel does not prevent flow of the fluid and therefore works in the same way transporting fluid. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The lack of a membrane in the channel in the figures of the disclosure as originally filed does not exclude the presence of a membrane in a channel in the prior art from reading on the instant claims. For more information regarding negative limitations in the claims, see MPEP 2173.05(i).

3. Applicant further argues that Kang et al. teach operating the device under a stream of urine and sample volumes on the order of 110 microliters and 200 microliters and the device of the present application is designed to detect analytes in sample volumes as small as 35 microliters. Applicant's argument is not persuasive because firstly, the claims do not provide any guidance as to what encompasses a "low" volume sample and does not require a specific sample volume and 110 or 200 microliters can be considered low volume samples. Secondly, the claim is drawn to a device of a platform, and the sample, and therefore any properties of the sample, ie. volume, is not a structural element of the claimed platform and performing detection on a low sample volume is an intended use of the platform. Therefore the platform taught by the prior art must only be capable of testing low volume liquid samples. The platform of the prior art comprises the required elements recited by the claim and the claims do not recite any structural elements that are different from the prior art and specifically allow the detection of sample volumes of exactly 35 microliters. The claimed invention must

result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE YU whose telephone number is (571)272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Yu/

Patent Examiner, Art Unit 1641